## DEFENSE HEALTH AGENCY

## **DEFENSE HEALTH AGENCY**7700 ARLINGTON BOULEVARD, SUITE 5101 FALLS CHURCH, VIRGINIA 22042-5101

September 27, 2016

Dr. Remington Nevin MuckRock DEPT MR 12509 PO Box 55819 Boston, MA 02205-5819

Dear Mr. Nevin:

Thank you for your Freedom of Information Act (FOIA) requests, received by the Defense Health Agency (DHA) on September 24, 2015. Your requests have been assigned Control Numbers 2016-008 and 2016-009. Please refer to this number in any future correspondence on this matter.

This letter is in further response to your FOIA requests for the following:

[All internal AFHSC and external DoD and non-DoD requests for analysis related to use of, or health effects related to use of, the drug mefloquine, received or processed by the Armed Forces Health Surveillance Center (AFHSC), from January 1, 2012 to July 1, 2014, as recorded in the "request manager" or a related tracking system, to include the results of any such analysis produced for AFHSC and external DoD and non-DoD customers as a result of such requests; and

All documents produced from September 2013 to July 2014 by the Armed Forces Health Surveillance Center related to the health effects of mefloquine use within DoD, to include the report referenced in multiple news reports as being in preparation as of September 2013, and expected to be completed by January 2014.]

In order to provide you the most detailed and informative response, our office searched for <u>any</u> records, reports, or final work products listed within the AFHSC Defense Medical Surveillance System (DMSS) request manager regarding the subject matter described above, with no date constraint. The results are described in the sheet titled "Mefloquine\_FOIA\_Release\_review." As you will note, this search resulted in 17 AFHSC DMSS reports.

We are providing 4 AFHSC DMSS final products/reports (R100268, R100353, and R110020) in full. In addition, we are providing R140095 with redaction pursuant to the FOIA exemption under 5 USC § 552(b)(6). Exemption (b)(6) applies to information that could reasonably be expected to constitute a clearly unwarranted invasion of the personal privacy of individuals, if released. DHA has determined that portions of this document are not releasable in accordance with DoD 6025.18R (DoD HIPAA regulation). Pursuant to FOIA exemption (b)(6),

therefore, the Agency redacted certain aggregate statistical data to de-identify information and protect the personal privacy of patients. Redacted copies of the requested documents are enclosed.

For five reports (R130223, R130263, R150039, R150046, and R150075), the AFHSC provided non de-identified raw data, which included PII/PHI, to the U.S. Army Pharmacovigilance Center. Due to the sensitive nature of the PHI dataset, we are withholding this data in full under FOIA exemption (b)(6).

In addition, we are withholding 3 AFHSC DMSS reports (R130345, 150155, and R160012) in full under (b)(5). The DHA has determined that the requested records are exempt from release under exemption (b)(5). Under Exemption (b)(5): the responsive documents are exempt from disclosure pursuant to FOIA exemption (b)(5) due to being internal records that are deliberative in nature and part of the decision-making process, containing opinions and recommendations. The general purpose of the exemption under 5 USC § 552(b)(5) is to prevent injury to the quality of agency decisions by: (1) encouraging open, frank discussions on matters of policy between subordinates and superiors; (2) protecting against premature disclosure of proposed policies before they are actually adopted; and (3) protecting against public confusion that might result from disclosure of reasons and rationales that were not in fact ultimately the grounds for an agency's action.

For R14016, instructions were drawn up for this retrospective cohort study. However, the data that would have been pulled for this request was never pulled. Essentially, the instructions for this report were open and closed without a data pull.

Lastly, our review of AFHSC records shows 4 reports under "MDR1 Polymorphs and Risk of Anxiogenic Mefloquine Adverse Events study" (R110138, R110176, R110376, and R110465), which are listed as reports previously requested and provided to you by the AFHSC.

If you are not satisfied with this action, you may appeal to the appellate authority, Defense Health Agency Office of General Counsel (National Capital Region Medical Directorate). To submit your appeal, you should write directly to:

Defense Health Agency Office of General Counsel National Capital Region Medical Directorate Attn: Mr. Paul T. Cygnarowicz 8901 Wisconsin Avenue (Building 27) Bethesda, MD 20889

Your appeal should be postmarked within 90 calendar days of the date of this letter, should cite the above referenced control number, and should be clearly marked "Freedom of Information Act Appeal."

Please note you have the right to seek dispute resolution services from the HA/DHA FOIA Public Liaison. Here is the contact information:

ATTN: Ms. Linda S. Thomas Chief, Freedom of Information Service Center Defense Health Agency 7700 Arlington Boulevard, Suite 5101 Falls Church, VA 22042-5101 Phone: 1-703-275-6363

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is:

Office of Government Information Services National Archives and Records Administration 8601 Adelphi Road–OGIS College Park, MD 20740-6001 ogis@nara.gov 202-741-5770 & 877-684-6448

If you have any questions on processing your request under the FOIA, please contact me at (703) 275-6009 or Mr. Paul Saenz at (703) 275-6013.

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Sincerely,

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FOIA Manager, Freedom of Information Service Center DHA Privacy and Civil Liberties Office